Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-7,10-11,14-15,22, 24,28-29 and 39-41are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Weid et al. (USP 4,129,381).

Weid et al. as characterized by Applicants 6/9/09 IDS is characterized as teaching all of the elements of the instant invention. See this characterization for the teachings of Weid et al.

Additionally, Weid et al. teach an automated method and apparatus for preparing a suspension of cells for cytological analysis. The sample is adjusted to contain the appropriate number of cells based upon a coulter counter which has been read on the "optical interrogating". Weid et al. teach if the sample has sufficient cellular concentrations it is OK for analysis. The Office has read this on the claimed "positive designator." If the sample does not contain sufficient cells, then more cells are added. The Office has read this on the claimed "manipulation designator" and " ... a manipulation to render the solution containing the initial sample satisfactory for slide preparation."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5-7,10-11,14-15, 21-24, 28-29 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isenstein et al. (US 2004/0253144).

See the appropriate paragraph of the 2/9/09 Office action for the teachings of Isenstein et al.

Isenstein et al. teach analysis of cervical/vaginal cells which has been read on the claimed "endocervical cells."

Additionally, Isenstein et al. teaches in paragraph[59] and figure 6 each slide is initially examined for the proper number of cells. If the cells on the slide fall within the desired range of 10 to 30 ASCUS+, the slide is accepted as a sample candidate. The acceptance of the slide has been read on the claimed attaching a positive designator" and these steps have been read on the claimed step "d) determining , ... sample has adequate concentration of cellular material ...". Paragraph[60] teaches if the sample is outside of the 10-30 ASCUS+ cell range the sample is either discarded or diluted respectively (see figure 6). This has been read on the claimed "manipulation designator" and these steps have been read on the claimed "g) attaching a manipulation designator ... a manipulation to render the solution containing the initial sample satisfactory for preparing a specimen slide." The claims differs from Isenstein et al. in the limitation "e) obtaining additional sample cytological sample from the patient to the added to the solution if the solution containing the initial sample does not have adequate concentration of cellular material;". Rather, Isenstein et al. only teach further dilution of a sample with too high a concentration of cells and not addition of more cells to a sample with too few cells.

It is well settled to use known techniques to improve similar methods in the same way. Isenstein et al. teaches if a sample has too high a concentration of cell, it can be diluted and a subjected to further processing. Isenstein et al. teach the sample with too low of a cellular concentration are discarded. It is desirable to use a minimal amount of sample. It would be desirable to avoid discarding the samples with too low cell concentration. It would be desirable to adjusting the cellular concentration of the sample by the addition of cells because it is known to adjust the cellular concentration in a sample for optimal analysis (e.g. Isenstein et al. teach adjusting the concentration of cells with too high of a concentration). It would have been within the skill of the art to modify Isenstein et al. and add more cells to a sample with too low a concentration to gain the advantages of using the minimal amount of sample for analysis.

Isenstein et al. are silent to placing a "marking on the vessel" to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."Id. at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify Isenstein et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

Claim 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weid et al.

See Weid et al. supra.

Weid et al. are silent to placing a "marking on the vessel" to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."Id. at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify Weid et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

Response to Arguments

Applicant's arguments filed 10/30/09 have been fully considered but they are not persuasive.

Applicant traverses the 35 USC 112 second paragraph rejections of claim 41 stating when the claim is properly read in light of the specification, one having ordinary skill in the art would clearly understand the claim. The instant claim is only limited to the

method steps where the sample concentration is inadequate. There is no guidance on what steps are performed if the sample is adequate. The Office has dropped the 35 USC 112 second paragraph rejections over claim 41 and is interpreting the claim as only covering the determination of an inadequate amount of sample.

Applicant states they cannot find the characterization of "Weid" references by the Office in the 6/9/09 NPL documents. For Applicant's convenience the characterization has been reproduced here:

"Independent claim 1 at least is not novel and do not involve an inventive step in light of the following prior art documents which were not available during the examiner first report.
D5
US 4129381 A (WIED et al.) 12 December 1978
(Cited in EPO search report for EP I668338, dated 1 October 2008)

D5 discloses an automated method of classifying at cytological sample (abstract) comprising providing a cytological sample in solution in a vessel (column I lines 32 to 54), optically, interrogating the solution (column 6 lines 43 to 68), comparing a result of said interrogation to a criterion (column 4 lines 10 to 20) and attaching a positive designator designating the sample as satisfactory for performing an intended assay and attaching a manipulation designator designating that the sample requires manipulation to render the sample adequate before performing the intended assay (column 1 lines 32 to 54; column 3 lines |9 to 30; column 7 lines 47 to 59).

Furthermore, it is considered that the features added by appended claims 2 to 24 are either disclosed in the above cited documents or relate to arrangements that are merely matters of design choice when the general technical knowledge about the state of the art is used and therefore cannot contribute to providing a patentable inventive step."

Applicant states Weid fails to teach the claimed step of obtaining a sample from a patient. The maintains that one having ordinary skill in the art would understand the cytological samples analyzed by Weid have come from a patient and have been properly read on the instant claims.

Applicant state Weid fails to teach the claimed attachment of a manipulation designator. The Office maintains Weid teaches in column 6 lines 43-68, ".... monitoring unit(37) , which can be a logic sequencer or microprocessor, ... programmed to terminate the sequence of operations when a desired concentration has been achieved

...". Weid clearly teaches programming that identifies an insufficient concentration and take the appropriate actions to obtain the desired concentration and has been properly read on the claimed "manipulation designator".

Applicant state Weid fails to teach the claimed step of "obtaining additional sample from the patient". The Office has consulted the specification and in the last paragraph on page 10 through page 11, the specification teaches the samples are obtained and placed in a vessel. Weid teaches in column 7 lines 20-46, "... the signal from the sensor cell(34) is used to control dispersion by regulating control means(40) and motor(29) ... " . The Office has read the claimed "obtaining additional sample from the patient" as obtaining additional sample from the vessel where it has been collected. Weid teaches dispensing unit(14) that contains the cellular sample is connected to the control means(40), actuator pump(16) and monitoring unit(37). As the sample is dispensed from dispensing unit(14) each additional increment of dispensed sample has been read on the claimed "obtaining additional sample from the patient."

Applicant state Weid fails to teach the claimed "temporal connection." The Office has read the claimed "temporal connection" as relating to the sequence of sample acquisition or a particular time when the sample is acquired. Weid teaches in column 7 lines 20-46, "... the signal from the sensor cell(34) is used to control dispersion by regulating control means(40) and motor(29) ... ". The sample is not dispensed all at once, but dispensed sequentially by means(40) over time and has been properly read on the claim 41.

Applicant's traverse the 35 USC 103 rejections over Isenstein stating the positive designator is attached before the slide is prepared. These remarks are not commensurate in scope with the pending claims that only require preparation of the sample within set parameters which is clearly taught by Isenstein.

Applicant's further state Isenstein teaches diluting or discarding the sample if the concentration of ASCUS+cells are not adequate which cannot be read on the claimed determination of an adequate concentration of cellular material. The Office maintains the instant claim language is sufficiently broad to have been properly read on the taught determination of cells taught by Isenstein. It is not clear how the instant claim language excludes the determination of any type of cells by the prior art.

Applicant's argue Isenstein fail to teach a sample from a patient. The Office maintains it is inherent the samples used in Isenstein come from a patient.

Applicant traverses the obviousness of the rejections over Isenstein. The issues of obviousness are directed to two different methods of obtaining the desired concentration of the sample and diluent:

Isenstein teaches adding the appropriate amount of diluent to the sample and if the sample concentration is too low, discarding the improperly diluted sample;

the instant claims add the appropriate amount of cells to achieve the desired concentration.

The Office has taken the position the same well known and expected results would have been achieved if instead of discarding a too dilute sample of Isenstein, more cell would be added to achieve the well known and expected results of a solution with

the proper concentration of cells. This also would have been advantageous to conserve the sample.

Applicant state Isenstein fails to teach the claimed "temporal connection." The Office has read the claimed "temporal connection" as relating to the sequence of sample acquisition or a particular time when the sample is acquired. Isenstein teaches the sample is not dispensed all at once, but dispensed sequentially over time and has been properly read on the claim 41.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday though Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797